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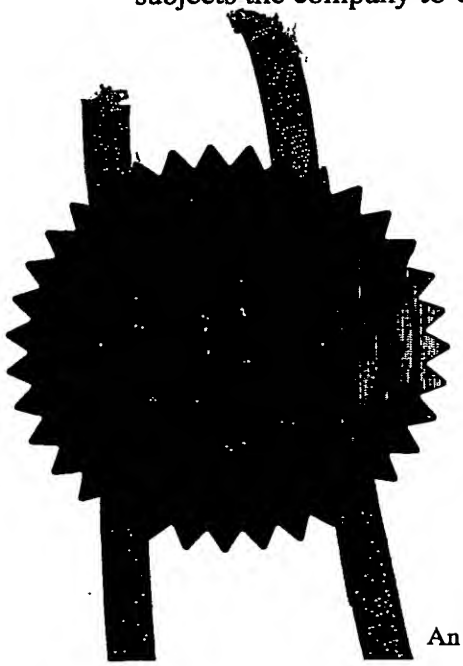

Signed P. Mahoney

Dated 1 April 2003

Patents Form 1/77

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THE PATENT OFFICE
18 APR 2002
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1/77

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(See the notes on the back of this form. You can also get an explanatory leaflet from the Patent Office to help you fill in this form)

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1. Your reference — A1428

19APR02 E712213-5 D02732
P1/7700 0.00-0208895.3

2. Patent application number *(The Patent Office will fill in this part)* — 0208895.3 — 18 APR 2002

3. Full name, address and postcode of the or of each applicant *(underline all surnames)*

ORDE LEVINSON

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Patents ADP number *(if you know it)* 7400989002

If the applicant is a corporate body, give the country/state of its incorporation

4. Title of the invention — IMPROVEMENTS RELATING TO A URINE SAMPLE COLLECTION DEVICE

5. Name of your agent *(if you have one)*

"Address for service" in the United Kingdom to which all correspondence should be sent *(including the postcode)*

ABLETT & STEBBING
CAPARO HOUSE
101-103 BAKER STREET
LONDON
W1U 6FQ

Patents ADP number *(if you know it)* **00006551001** ✓

6. If you are declaring priority from one or more earlier patent applications, give the country and the date of filing of the or of each of these earlier applications and *(if you know it)* the or each application number

Country	Priority application number *(if you know it)*	Date of filing *(day / month / year)*

7. If this application is divided or otherwise derived from an earlier UK application, give the number and the filing date of the earlier application

Number of earlier application	Date of filing *(day / month / year)*

8. Is a statement of inventorship and of right to grant of a patent required in support of this request? *(Answer 'Yes' if:*

a) any applicant named in part 3 is not an inventor, or
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Continuation sheets of this form	0
Description	9
Claim *(s)*	2
Abstract	0
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Priority documents	
Translations of priority documents	
Statement of inventorship and right to grant of a patent *(Patents Form 7/77)*	
Request for preliminary examination and search *(Patents Form 9/77)*	
Request for substantive examination *(Patents Form 10/77)*	
Any other documents *(please specify)*	

11. I/We request the grant of a patent on the basis of this application.

Signature — Date

ABLETT & STEBBING — 17 April 2002

12. Name and daytime telephone number of person to contact in the United Kingdom

G K ABLETT / S J SUÈR (0207-935-7720)

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IMPROVEMENTS RELATING TO A URINE SAMPLE COLLECTION DEVICE

The present invention relates to a urine sample collection device and in particular to a urine sample collection device which facilitates the taking of a mid stream urine (MSU) sample.

The Applicant is the proprietor of earlier patent application WO-A-01/74275. This application details the various reasons why urine samples are collected and the uses there are for the results of the analysis of the collected sample.

Figure 1 illustrates a urine sample collection device 1 based on the disclosure of this patent application. The device has a urine receiving portion or urine receptor generally identified by reference numeral 2. This comprises a surface 7 which defines at one end an outlet aperture 2 and which flares out to define at its other end a rim 8 forming a perimeter of an inlet area into which a user urinates. The various forms of the receptor are described in more detail in the aforementioned patent application. The outlet aperture is coupled to one end of a generally elongate hollow tubular member or pipe portion 4. The other end of the tubular member is open. The tubular member 4 narrows along its length and the end remote from the outlet aperture 3 defines a generally oblong excess outlet aperture 6. A sample container coupling 5 comprises a short hollow stub like tube which is formed with a passage therethrough which meets an opening in the centre of the side of the tubular member. The sample container coupling 5 is located along the tubular member 4 to be spaced from the outlet aperture 3. The sample container coupling is formed to provide a push fit for a standard urine sample collection container or bottle (not shown). The sample container coupling 5 is located and formed such that the sample container is

orientated vertically downwards during use.

In use, a standard tubular urine sample collection container (not shown) is pushed onto the sample container coupling 5. A female user then locates the receptor 2 against their body to cover the urethra as explained more fully in the aforementioned patent application. A male user locates the end of their penis into the receptor.

The user then urinates and urine flows along the tubular member and flows both into the sample urine sample collection container and out of the excess outlet aperture 6. Once the collection container is full, the user can simply finish urinating because excess urine flows out of the excess outlet 6. Alternatively, the user can withdraw the device 1 and continue to urinate, but this increases the likelihood of contamination to their hands.

In this type of device, the urine flows through the device and out of the excess outlet aperture with a proportion of that urine flow being collected in the collection container via sample container coupling 5. This through flow type of device differs from devices where all the urine flow is directed straight into a collection container.

A view has been expressed by medical personnel that it is important to sample the urine mid stream. One justification for obtaining a mid stream urine (MSU) sample is that if there is any initial contamination in or around the urinary tract or urethra, such contamination will be flushed out at the start of urination. Another justification is that a mid stream sample is more representative of the contents of the bladder than that at the start of urination and is less dependent on personal hygiene.

In this case, if an MSU sample is to be obtained, it is important not to collect the initial flow at the start of urination and immediately thereafter. Unfortunately, with the

device shown in figure 1, it is not possible to guarantee that a proportion of this initial flow will not be collected.

It is therefore an object of the present invention to provide a urine sample collection device which is less likely to collect a proportion of the initial flow of urine following the start of urination, and which preferably remains straightforward and inexpensive to manufacture.

According to the present invention there is provided a urine sample collection device comprising:-

a urine receptor having a surface which flares out from an outlet aperture to a rim defining a perimeter of an inlet area into which a user urinates;

a generally elongate tubular member extending from said receptor outlet aperture to an open end, the tubular member having an opening formed in the side thereof;

a coupling means for releasably mounting a urine collection container, the coupling means having a passage extending therethrough which meets said opening whereby urine can flow from the tubular member into a mounted container; and

a flow director located at or adjacent said opening and formed to direct urine past the opening.

Preferably the flow director comprises a projection towards the axis of the tubular member.

In one embodiment, the projection is provided upstream of the opening.

In another embodiment, the projection is also formed downstream of the opening.

In one preferred embodiment, the projection upstream of the opening has an inclined surface.

In another preferred embodiment, the projection upstream of the opening comprises a wall which extends across the tubular member to an extent corresponding to the upstream edge of said opening.

Conveniently, the flow director is formed to channel the urine flow along either side of the aperture.

It is preferred that the tubular member tapers to a smaller cross-section at said open end.

Examples of the invention will now be described with reference to the following figures, in which:-

Figure 1 shows an oblique perspective view of a known urine sample collection device;

Figure 2 shows a perspective side view of a tubular member part of an embodiment of the present invention;

Figure 3 shows the cross-sectional views along the line C-C of figure 2;

Figure 4 shows the cross-section along the line D-D of figure 2;

Figure 5 illustrates a side view of another embodiment of a urine sample collection device;

Figure 6 illustrates a plan view of the urine receiving portion of figure 5 as viewed along the axis of the tubular member;

Figure 7 illustrates a cross-sectional side view taken along the length of the tubular member part of figure 5 omitting the urine receptor.

Component parts which are common amongst the figures bear common reference numerals.

It is considered that if a through flow type of device as shown in figure 1 is to obtain a mid stream urine sample, it is necessary to ensure that as little as possible of the initial urine flows into the collection container. It is considered that proportion of urine entering the collection container, at least during the initial flow, will be a function of the area of the opening to the passage through the sample container coupling 5, that is to say, the opening of the passage onto the tubular portion 4, and the velocity (and

hence momentum) of the urine flow upstream of the coupling. The former can be designed whilst the latter will be influenced by the bladder of the user and by gravity consequent to the angle of the urine flow in the tubular portion relative to vertical.

One option to reduce the proportion of urine entering the collection container during the initial flow would be to make the aforementioned area smaller and/or increase the velocity of the urine flow. Unfortunately, this tends to lead to problems with the overall urine collection to the point that the collection container remains substantially empty.

Figure 2 illustrates an oblique perspective view of a portion of a tubular member 4' corresponding to the tubular member 4 shown in figure 1. The precise form of the receptor is not material to the present invention. In this embodiment, the tubular member has a generally square cross section as shown in the drawings but is not limited thereto. The tubular member has a base 20 from which a sample container coupling 5' extends. The sample container coupling 5' has a passage therethrough which meets an opening formed in the base of the tubular member 4', the opening defining a planar area 21. Thus, urine flowing down the tubular member 4' can pass down into a collection container (not shown) fitted to the coupling 5'. The flow of urine in the tubular member 4' is indicated by an arrow U, substantially along the axis of the tubular member.

In this embodiment, the base 20A which is upstream of the area 21 is formed to include an inclined surface or ramp 24 which leads up to the area 21. The ramp therefore projects towards the axis of the tubular member. The area 21 is substantially parallel to the surface of upstream base 20A but is not in the same plane. Downstream of the area 21, the central member of the base of the tubular member 4' along the

axis thereof defines a plateau surface 22 which is on the plane defined by the area 21. Towards either edge of this plateau surface, channels 23 are formed which extend either side of the area 21 to meet the base 20 which is upstream of the area 21. The base of the channels 23 is on the plane of the base 20 which is upstream of the area 21.

Thus, when urination starts, if the urine is flowing slowly, urine will flow along the channels 23 and pass either side of the area 21 so that none of this initial flow will pass into the collection container through the area 21. As the urine flow builds up in velocity, it will tend to rise up the ramp 24. Eventually, the urine will tend to travel entirely up the ramp and will be directed over the area 21. However, due to the velocity, the urine will tend not to fall onto the area but instead pass completely over it so that none of this flow will pass into the collection container through the area 21. Consequently, the channels and ramp 24 function to direct the flow of urine past the area 21.

Generally speaking, the volume of urine entering the tubular member 4' will eventually be greater than that leaving through the aperture 6. Thus, a front of fluid begins to "back up" along the tubular member. When the front reaches the area 21, the collection container will begin to fill. Thus, the early part of the urine flow does not pass into the collection container so that an MSU sample is collected.

Consequently, by having a ramp 24 to direct the urine to pass over the area 21 facilitates the collection of an MSU sample. In addition, by having the channels 23, if the initial urine flow is very slow, for example due to urological diseases or infections which can cause pain or for those with voiding difficulties or obstructions, this slow moving urine is directed either side of the area 21 and is not collected. In addition, in cases where imperfect personal hygiene tends

to contamination the early part of a urine sample, this contaminated part of the urine flow is not collected.

The present invention is capable of considerable modification, the detailed embodiments of which will be readily apparent to those skilled in the art. For example, whilst the present embodiment has been described to include channels 23, these can be omitted such that the ramp 24 extends across the width of the base 20 if very slow urine flow is not to be considered a problem during urine collection. It will be appreciated that the angle and size of ramp can be varied. Whilst a ramp has been described as the flow director, a wall can be used which extends across the base 24 to an extent corresponding to the upstream edge of the area 21 such that the area is masked from the direct flow of urine along the tubular member 4'. The wall can also be V-shaped pointing upstream so that slow moving urine is directed around the area 21. Alternatively, the coupling 5' can be made such that it extends through the base 20 whereby its upper edge defines the area 21 which is in a plane located displaced relative to the base 20.

In this respect, referring to the urine sample collection device 1'' shown in figures 5 to 7, the urine receptor 2'' is substantially identical to that shown in figures 1 to 4. However, it will be noted that the device has a tubular member 4'' which comprises a constant circular cross-section tube, that is to say, it does not narrow between the urine receptor 2'' and the excess outlet aperture 6''.

A sample container coupling 5'' is located as with figures 1 to 4. As can be seen from figures 6 and 7, the outer surface of the coupling 5'' has a portion 10 at the end onto which a sample container can be attached, this portion having a circular cross-section outer surface. The outer surface of the coupling 5'' also has a portion 12 where the coupling

meets the tubular member 4''. The portion 12 has a larger circumference than the portion 10, the portions 10 and 12 meeting at an elbow 11.

A passage is formed through the coupling 5'' which comprises a circular cross-section tube which is split into two separate channels 13 and 14 having respective semi-circular cross-sections, as can be seen from figure 6. One end (the lower end) of the channels 13 and 14 extend equally from the lower edge of the portion 10, as can be seen from figure 7. The other end (the upper end) of the channels 13 and 14 extend through the base of and into the tubular member 4''. The upper edge of the channel 14 extends further into the tubular member 4'' than the channel 13 and is located on the side towards the outlet aperture 6'' (downstream). The upper edge of the channel 13 defines a semi-circular area 21'' whilst the upper edge of the channel 14 defines a semi-circular area 15.

When urination starts, if the urine is flowing slowly, urine will flow down the tubular member 4'' and will flow either side of the channels 13 and 14 extending into the member 4''. Thus, none of this initial flow will pass into a collection container. As the urine flow builds up in velocity, the flow in the tubular member 4'' will become deeper until the depth reaches a value of "a", which comprises the distance (the height) of the upstream edge of the channel 13 from the base of the tubular member 4'', as shown in figure 7. At this point, urine will start to flow into the area 21'' and down through the channel 13 into the collection container. The downstream channel 14 acts as an air vent for air to escape from the collection container as it fills. The upper edge 15 has a height from the base of the tubular member 4'' which is greater than "a" so that urine does not normally flow down channel 14. The height "a" is preferably in the range of 20 to

60% of the height of the tubular member 4'' at the point of the coupling 5''. In this case, the tubular member has a diameter "d" and hence a = 20-60% of d. Thus, the area 21'' is effectively spaced from the base or lower surface of the tubular member 4'' by an a distance which provides a wall against slow flowing urine.

It will be apparent that an air vent for the collection container can be provided in a different manner.

The present invention is produced from a plastics material injected into a tool having a shaped insert to form the tubular member 4'. In the described embodiment of figures 2 to 4, the tubular insert can be a single piece that is withdrawn in the direction of the receptor 2. If a two piece insert is used, it is possible to have the area 21 made such that it is in the plane of the base 20 but the top edge of the ramp 24 remains displaced from the plane of the base.

By having a construction as shown in the embodiment of figures 5 to 7 and with a tubular member 4'' which does not narrow, it is possible to produce a tool in which a shaped insert can form the tubular member 4'' by insertion into opposing ends of thereof.

CLAIMS

1. A urine sample collection device comprising:-

a urine receptor having a surface which flares out from an outlet aperture to a rim defining a perimeter of an inlet area into which a user urinates;

a generally elongate tubular member extending from said receptor outlet aperture to an open end, the tubular member having an opening formed in the side thereof;

a coupling means for releasably mounting a urine collection container, the coupling means having a passage extending therethrough which meets said opening whereby urine can flow from the tubular member into a mounted container; and

a flow director located at or adjacent said opening and formed to direct urine past the opening.

2. Apparatus according to claim 1 wherein the flow director comprises a projection towards the axis of the tubular member.

3. Apparatus according to claim 2 wherein the projection is provided upstream of the opening.

4. Apparatus according to any one of claims 3 wherein the projection is also formed downstream of the opening.

5. Apparatus according to claim 3 or 4 wherein the projection upstream of the opening has an inclined surface.

6. Apparatus according to claim 3 or 4 wherein the projection upstream of the opening comprises a wall which extends across the tubular member to an extent corresponding to the upstream edge of said opening.

7. Apparatus according to any preceding claim wherein the flow director is formed to channel the urine flow along either side of the aperture.

8. Apparatus according to claim 2 wherein the projection towards the axis of the tubular member comprises

the passage of the coupling means, the passage extending into the tubular member and presenting an area within the tubular member into which urine can enter and flow into the collection container.

9. Apparatus according to claim 8 wherein the passage of the coupling means extends into the tubular member by an amount corresponding to between 20 and 60% of the height of the tubular member.

10. Apparatus according to claim 8 or 9 wherein the area comprises a semi-circle and wherein the extension of the passage into the tubular member is greater downstream than upstream.

11. Apparatus according to any one of claims 8 to 10 wherein the coupling means includes a further passage extending therethrough which meets said opening to present an area from which air in the collection container can escape into the tubular member.

12. Apparatus according to claim 11 wherein the further passage of the coupling means extends into the tubular member by an amount which is greater than the first mentioned passage.

13. Apparatus according to any preceding claim wherein the tubular member tapers to a smaller cross-section at said open end.

14. A urine sample collection device substantially as herein described with reference to figures 2 to 7.

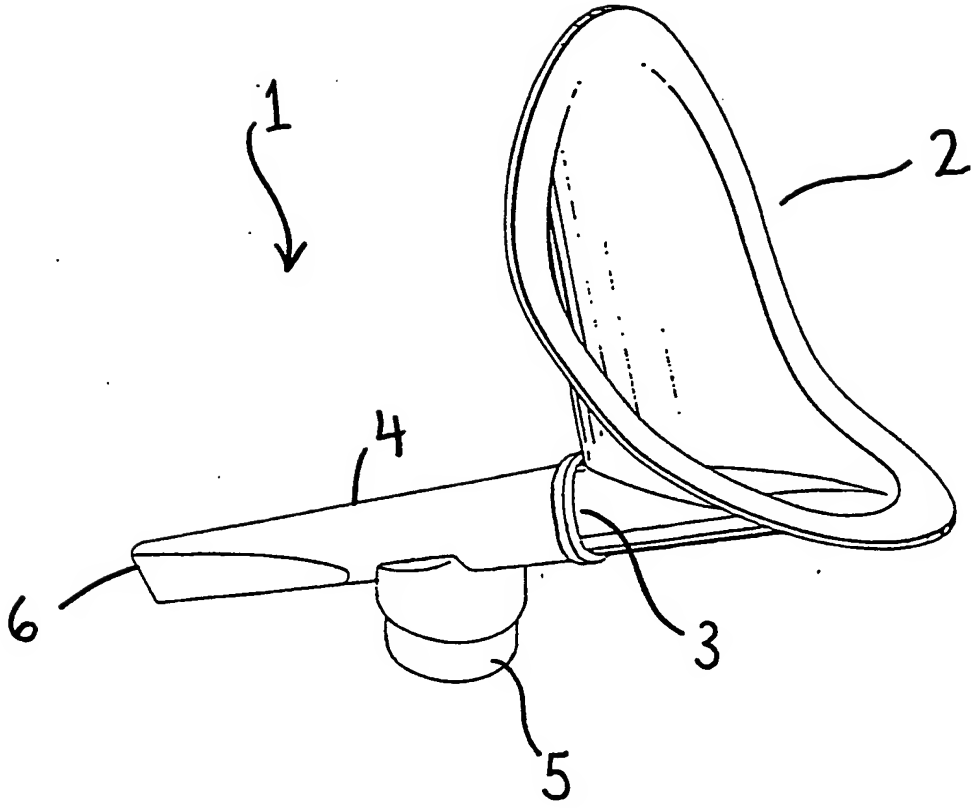

FIGURE 1

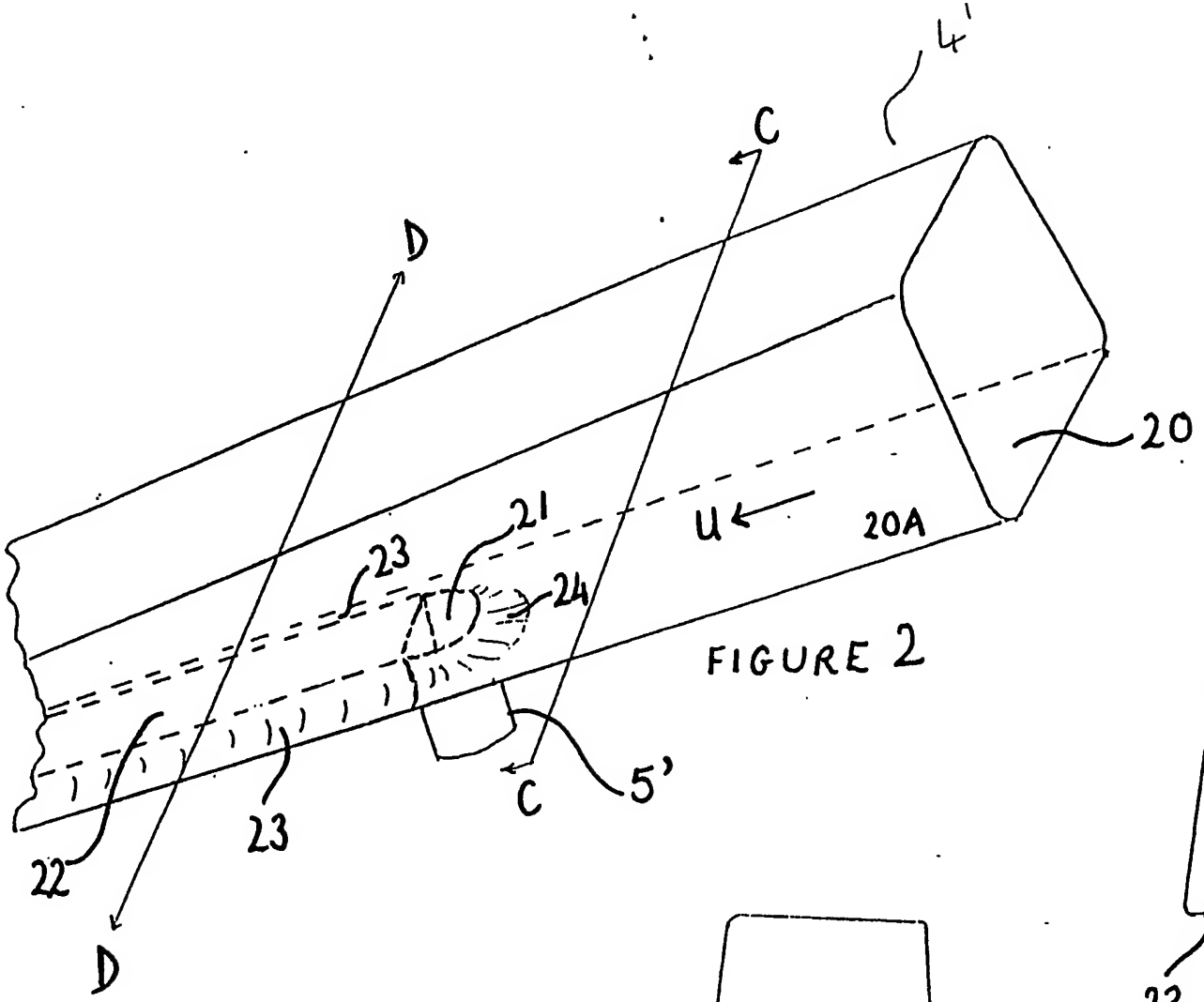

FIGURE 2

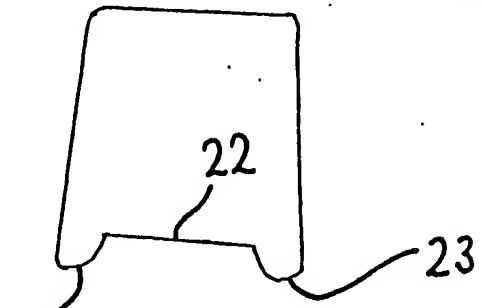

FIGURE 3

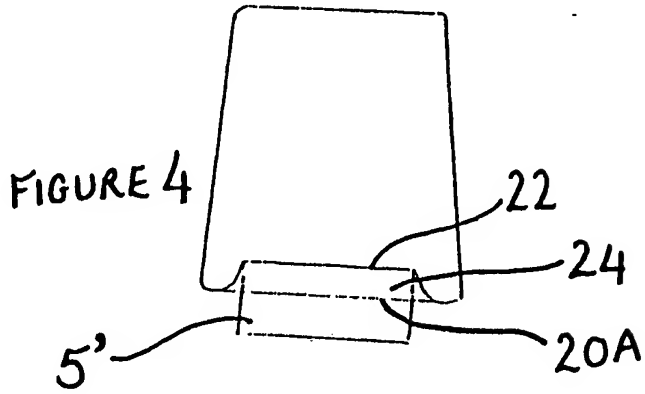

FIGURE 4

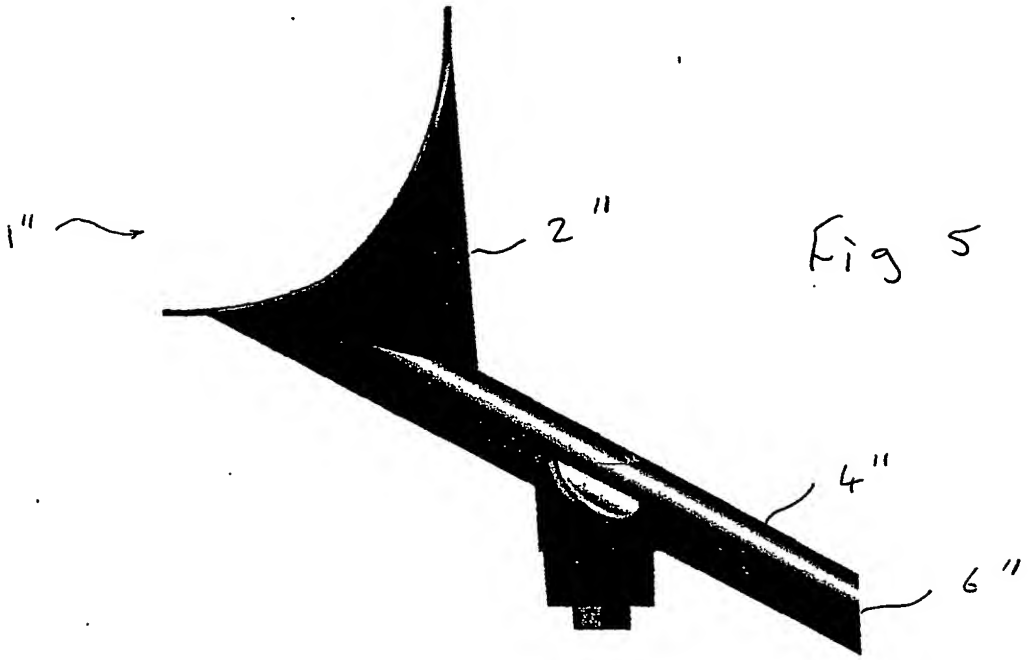

Fig 5

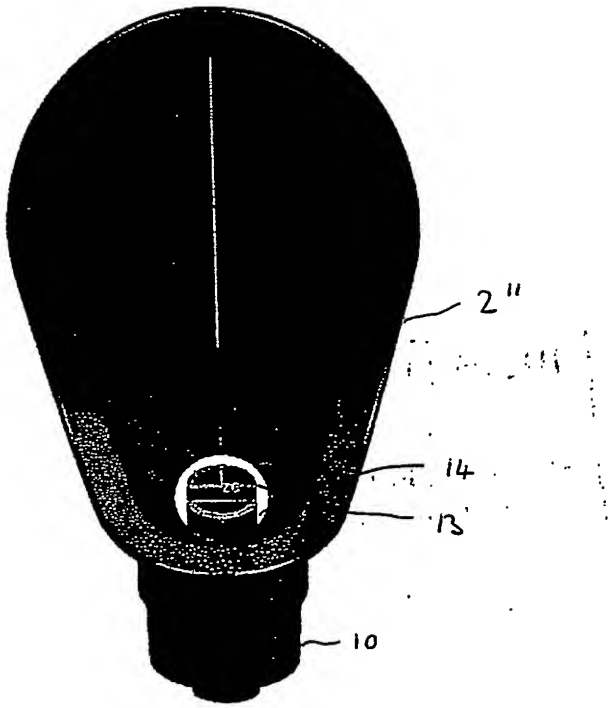

Fig 6

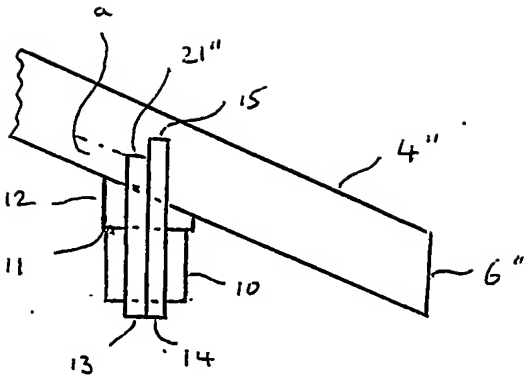

Fig 7